510(k) Summary

APR 0 9 2013

Applicant:

Medtronic Ireland
Parkmore Business Park West
Galway
Ireland

Submission Correspondent:

Deirdre McMahon
Senior Regulatory Affairs Specialist
Medtronic Ireland
Parkmore Business Park West
Galway
Ireland

Telephone:

+353-91-708968

Fax:

+353-91-708672

E-mail:

deirdre.mcmahon@medtronic.com

Date Prepared:

September 28, 2012

Name of the device, including the trade or proprietary name, if applicable, the common or usual name, and the classification name, if known

Proprietary Names:

- Attain Command™ + SureValve™ Left Heart Delivery System
- Attain Command™ + SureValve™ Guide Catheters for Left Heart Delivery
- Attain Select™ II + SureValve™ Delivery Catheter System

Common Names:

- Left Heart Delivery System
- Guide Catheters for Left Heart Delivery
- Delivery Catheter System

Device Classification Name:

Catheter, Percutaneous
Class II, 21 CFR 870.1250

Product Code:

DQY

Substantially Equivalent Device(s):

The Attain Command™ + SureValve™ Left Heart Delivery System and Attain Command™ + SureValve™ Guide Catheters for Left Heart Delivery are similar to the following predicates with respect to intended use, design and technology:

- Attain Command™ 6250 Left Heart Delivery Systems (K080428, K090659)
- Attain Command™ 6250 Guide Catheters for Left Heart (K080428, K090659)

The Attain Select™ II + SureValve Delivery Catheter System is similar to the following predicate with respect to intended use, design and technology:

- Medtronic Attain Select™ II 6248DEL Delivery Catheter System (K053431)

Device Description:

The Attain Command™ + SureValve™ Left Heart Delivery System and Attain Command™ + SureValve™ Guide Catheters for Left Heart Delivery are intended for introducing transvenous devices and leads into vessels of the left heart via the coronary sinus.

The Attain Command™ + SureValve™ Left-Heart Delivery System kits each contain two outer guide catheters with an integrated hemostasis valve (SureValve™), up to two valve tools, one dilator, one guide wire, and one slitter. The Attain Command™ + SureValve™ Left-Heart Delivery System is available in two models:

- Attain Command™ + SureValve™ 6250VC Left Heart Delivery System
- Attain Command™ + SureValve™ 6250VS Left Heart Delivery System

With the exception of the two guide catheters, all system components packaged in each kit are identical. Each guide catheter model is different with respect to the guide catheter shape and length.

The Attain Command™ + SureValve™ Guide Catheters for Left Heart Delivery individual packs each contain one guide catheter with an integrated hemostasis valve (SureValve™), up to two valve tools, and one dilator. The Attain Command™ + SureValve™ Guide Catheters for Left Heart Delivery are available in 12 models:

- Attain Command™ + SureValve™ 6250V-45S Guide Catheter for Left Heart Delivery
- Attain Command™ + SureValve™ 6250V-50S Guide Catheter for Left Heart Delivery
- Attain Command™ + SureValve™ 6250V-57S Guide Catheter for Left Heart Delivery
- Attain Command™ + SureValve™ 6250V-AM Guide Catheter for Left Heart Delivery
- Attain Command™ + SureValve™ 6250V-EH Guide Catheter for Left Heart Delivery
- Attain Command™ + SureValve™ 6250V-EHXL Guide Catheter for Left Heart Delivery
- Attain Command™ + SureValve™ 6250V-MB2 Guide Catheter for Left Heart Delivery
- Attain Command™ + SureValve™ 6250V-MB2X Guide Catheter for Left Heart Delivery
- Attain Command™ + SureValve™ 6250V-MP Guide Catheter for Left Heart Delivery
- Attain Command™ + SureValve™ 6250V-MPR Guide Catheter for Left Heart Delivery
- Attain Command™ + SureValve™ 6250V-MPX Guide Catheter for Left Heart Delivery
- Attain Command™ + SureValve™ 6250V-3D Guide Catheter for Left Heart Delivery

Each model is different with respect to the guide catheter shape and length and dilator length.

The Attain Select™ II + SureValve™ delivery catheter system is designed to facilitate left-heart lead delivery to a desired cardiac vein. The Attain Select™ II + SureValve™ delivery catheter system is indicated for the delivery of contrast medium and transvenous devices to the coronary sinus and left-heart venous anatomy. The delivery catheter system is indicated for use with outer guide catheters. Together, the catheters function as a telescoping system that can provide additional subselecting capabilities.

The delivery catheter system consists of a delivery catheter with an integrated hemostasis valve (SureValve™), an inner catheter, and up to two valve tools. The Attain Select™ II + SureValve™ delivery catheter system is available in 8 models:

- Attain Select™ II + SureValve™ 6248V-90 Delivery Catheter System
- Attain Select™ II + SureValve™ 6248V-90S Delivery Catheter System
- Attain Select™ II + SureValve™ 6248V-90L Delivery Catheter System
- Attain Select™ II + SureValve™ 6248V-130 Delivery Catheter System
- Attain Select™ II + SureValve™ 6248V-130L Delivery Catheter System
- Attain Select™ II + SureValve™ 6248V-90P Delivery Catheter System
- Attain Select™ II + SureValve™ 6248V-90SP Delivery Catheter System
- Attain Select™ II + SureValve™ 6248V-130P Delivery Catheter System

The Attain Select™ II + SureValve™ inner catheter is identical for all configurations. Each model is different with respect to delivery catheter shape and length.

Intended Use:

Attain Command™ + SureValve™ Left Heart Delivery System and Attain Command™ + SureValve™ Guide Catheters for Left Heart Delivery:

The left-heart delivery system is intended for introducing transvenous devices and leads into vessels of the left heart via the coronary sinus.

Attain Select™ II + SureValve™ Delivery Catheter System:

The Attain Select™ II + SureValve™ delivery catheter system is indicated for the delivery of contrast medium and transvenous devices to the coronary sinus and left-heart venous anatomy. The delivery catheter system is indicated for use with outer guide catheters.

Summary of the technological characteristics of the device compared with the predicate device:

Attain Command™ + SureValve™ Left Heart Delivery System and Attain Command™ + SureValve™ Guide Catheters for Left Heart Delivery:

The Attain Command™ + SureValve™ Left Heart Delivery System and Attain Command™ + SureValve™ Guide Catheters for Left Heart Delivery are designed to facilitate lead implantation in the left heart, via the coronary sinus. The left-heart delivery systems are intended for introducing transvenous devices and leads into vessels of the left heart via the coronary sinus.

The outer guide catheter is designed to gain and maintain access to the coronary sinus and facilitate passage of transvenous devices and placement of leads into the cardiac veins, while the dilator facilitates passage of the outer guide catheter into the venous system. Additional accessories packaged with the kits include the guide wire and slitter; the guide wire is intended to direct the outer guide catheter or dilator through a blood vessel, while the slitter is intended to remove the outer guide catheter following transvenous device implantation.

Attain Select™ II + SureValve™ Delivery Catheter System:

The Attain Select™ II + SureValve™ delivery catheter system is designed to facilitate left-heart lead delivery to a desired cardiac vein. The Attain Select™ II + SureValve™ delivery catheter system is indicated for the delivery of contrast medium and transvenous devices to the coronary sinus and left-heart venous anatomy.

The delivery catheter system is indicated for use with outer guide catheters. The delivery catheter aids in subselection and provides a pathway for the delivery of transvenous devices such as leads, inner catheters, and guide wires. It has a radiopaque flexible tip to facilitate viewing during fluoroscopy.The inner catheter supports the delivery catheter and aids in subselection. The inner catheter has a radiopaque tip and allows delivery of a guide wire or contrast solution.The delivery catheter system is used with an outer guide catheter, which is the sheath used to gain coronary sinus access. Together, the catheters function as a telescoping system that can provide additional subselecting capabilities.

Summary of non-clinical performance data:

Testing was performed to support the equivalency of the Attain Command™ + SureValve™ and Attain Select™ II + SureValve devices to their respective predicate devices. The following non-clinical test summaries are presented below:

- *In Vitro* Bench Testing
- Biocompatibility
- Sterilization

***In Vitro* Bench Tests:**

The following *in vitro* bench tests were performed:

- Dimensional Testing
- Catheter Safety & Performance Testing
- Component/Accessory Safety & Performance Testing
- Interface Safety & Performance Testing (compatibility with transvenous devices)
- Packaging Qualifications
- Shelf Life Testing

The Attain Command™ + SureValve™ and Attain Select™ II + SureValve devices met all specified design and performance requirements.

Biocompatibility Validations:

Biocompatibility of the Attain Command™ + SureValve™ and Attain Select™ II + SureValve devices was evaluated in accordance with ISO 10993-1:2009, *Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process*, and testing was completed in accordance with FDA Good Laboratory Practice (GLP) regulations (21 CFR, Part 58).

Biocompatibility tests supporting biocompatibility of the Attain Command™ + SureValve™ and Attain Select™ II + SureValve devices were appropriate for an implant device that is an externally communicating device in limited contact with circulating blood (<24 hours).

Biocompatibility data supporting the Attain Command™ + SureValve™ and Attain Select™ II + SureValve devices included the following assessments:

- Cytotoxicity Study using ISO MEM Elution method
- ISO Maximisation Sensitisation Study
- ISO Acute Intracutaneous Reactivity
- ISO Acute Systemic Toxicity
- USP Material Mediated Pyrogen Study in Rabbits
- ASTM *In-vitro* Hemolysis
- ASTM Partial Thromboplastin Time (PTT) Coagulation Testing
- C3a Complement Activation Assay Study
- Sc5b-9 Complement Activation Assay Study
- In Vivo Thromboresistance Study in the Dog, Jugular Vein
- USP Physicochemical Tests for Plastic (Aqueous)
- Physicochemical Tests for Plastic (Non-Aqueous)

Biocompatibility test results indicate that the Attain Command™ + SureValve™ and Attain Select™ II + SureValve™ devices are biocompatible and suitable for their intended use.

Sterilization Validations:

Sterilization validation testing has been completed in accordance with ISO 11135-1 and EN556-1. The results of this testing confirm that the Attain Command™ + SureValve™ and Attain Select™ II + SureValve™ devices can be sterilized at the contract sterilization facility to successfully achieve a minimum Sterility Assurance Level (SAL) of 10^{-6}.

Summary of clinical performance data:

No clinical investigation has been performed for the Attain Command™ + SureValve™ or Attain Select™ II + SureValve devices.

Conclusion:

Through the data and information presented, Medtronic Ireland considers the Attain Command™ + SureValve™ and Attain Select™ II + SureValve devices to be substantially equivalent to their respective predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 9, 2013

Medtronic Ireland
c/o Ms. Deirdre McMahon
Parkmore Business Park West
Galway, EI EL

Re: K123153
Trade Name: Attain Command™ + SureValve™ Left Heart Delivery System
Attain Command™ + SureValve™ Guide Catheters for Left Heart Delivery
Attain Select™ II + SureValve™ Delivery Catheter System
Regulation Number: 21 CFR 870.1250
Regulation Name: Catheter, Percutaneous
Regulatory Class: Class II
Product Code: DQY
Dated: March 22, 2013
Received: April 01, 2013

Dear Ms. McMahon:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Owen P. Faris -S

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K123153

Device Name: Attain Command™ + SureValve™ Left Heart Delivery System

Attain Command™ + SureValve™ Guide Catheters for Left Heart Delivery

Indications for Use:

The Attain Command™ + SureValve™ Left Heart Delivery System and Attain Command™ + SureValve™ Guide Catheters for Left Heart Delivery are intended for introducing transvenous devices and leads into vessels of the left heart via the coronary sinus.

Prescription Use X AND/OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Owen P. Faris -S
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